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## Spain

### Agricultural Biotechnology Annual

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**Report Highlights:**

This report offers an outlook of the situation of agricultural and animal biotechnology with regard to cultivation, research, policy and marketing environment in Spain. Spain is the EU's largest biotech crop grower, and it imports a large quantity of feed products to meet the needs of its robust livestock industry. As a consequence, any change in the cultivation or trade legal framework has a significant impact in Spain's agribusiness.

**Disclaimer:** Spain, as a member of the European Union (EU), conforms to EU directives and regulations on biotechnology. It is therefore recommended that this report be read in conjunction with the EU-27 consolidated report.

**Abbreviations used in this report:**

EC European Commission  
EU European Union  
FAS Foreign Agricultural Service  
MS EU Member State(s)  
MT Metric ton (1,000 kg)  
Ha Hectares  
GMO Genetically Modified Organism

**Section I. Executive Summary:**

MON810 corn has been commercially grown in Spain since 1998. Total area planted to corn varies every year based on water availability, prices paid to farmers and competition from alternative crops. Since 2006, GE corn area has varied following the fluctuations of total corn in Spain. At present, Spain remains the largest grower on GE corn within the European Union, representing approximately 80 percent of total MON810 planted in the European Union.

As it regards to cultivation opt out, Spain's main concerns are the compatibility with the common internal market and the compliance with WTO rules.

There is no commercial GE crop plot register implemented, however, a draft regulation to force those farmers who grow GE crops to register their plots is currently being discussed. To date, coexistence has been managed following the good agriculture practices promoted by ANOVE, the National Association of Seed Breeders.

Field trials are also permitted in Spain, and they are authorized in a case by case basis. About 28 field trials to be carried out throughout 2011 have been notified to the Ministry of Environment and Rural and Marine Affairs (MARM) for its approval up to July 2011.

Spain's has traditionally taken a science-based approach biotech regulatory process. With the EU policy agenda and rules being set in Brussels, Spain works hard to ensure that science is an important ingredient in the process, but in the end, Spain must abide by the EU-wide legislation.

There are two relevant Authorities that weight-in on Spain's biotechnology decision making process, which are the National Biosafety Commission (CNB) and the Inter-ministerial Council for GMOs (CIOMG). The CNB takes a scientific approach, whereas CIOMG's approach is technical. Civil society participation is encouraged by the Consultative Committee for GMO (CPOGM) ascribed to the Inter-ministerial Council, whose role is to reassure participation of civil society representatives.

Its structural shortfall of grains and oilseeds makes Spain's trade, feed and livestock sectors traditional supporters of biotech. Most of Spain's farmers associations are also in favor of planting biotech crops. The use of agricultural technologies such as biotechnology or irrigation systems to improve competitiveness and obtain consistent output levels are positively perceived and defended by a large majority of the farming sector.

According to Eurobarometer 2010, Spain's index of optimism for biotechnology/genetic engineering remains among the highest within the EU (74 percent) and so remains Spain's support for GM food (35 percent of respondents agreed or totally agreed that GM food should be encouraged).

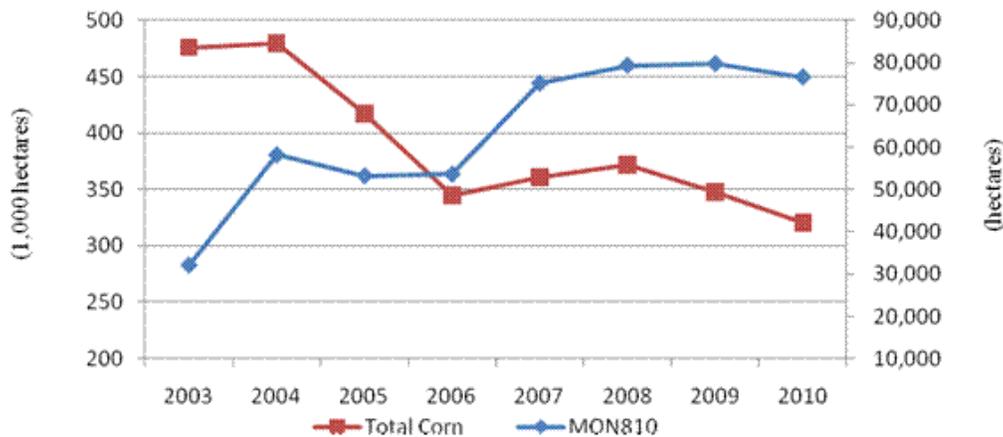
As it pertains to animal biotechnology, there is no known research or development of GE animals for the food market.

## Section II. Plant Biotechnology Trade and Production:

### Commercial Cultivation

While in the EU there are two biotech events approved for cultivation, only MON810 corn is cultivated in Spain. MON810 corn has been commercially grown in Spain since 1998 - the longest practical experience in cultivating biotech events in the EU. Spain has the largest area planted to GM crops within the EU, representing approximately 80 percent of total MON810 planted in the European Union.

**Graph 1. Total corn and MON 810 corn area on Spain.**



Source: FAS Madrid based on Ministry of Environment and Rural and Marine Affairs data.

Note: Since 2009, the Spanish Ministry of Environment and Rural and Marine Affairs (MARM) publishes GM crop area including not only corn varieties in the national register in the EU common catalogue, but also those varieties granted with a provisional authorization. Figures from 2009 on in the chart above have been updated accordingly.

Total area planted to corn varies every year based on water availability, prices paid to farmers and competition from alternative crops. Since 2006, GM corn area has varied following the fluctuations of total corn in Spain.

For 2011 a larger area planted to BT corn is anticipated, based in last year’s high pressure of the corn borer in the main corn growing areas along with the overall increase of area planted to corn.

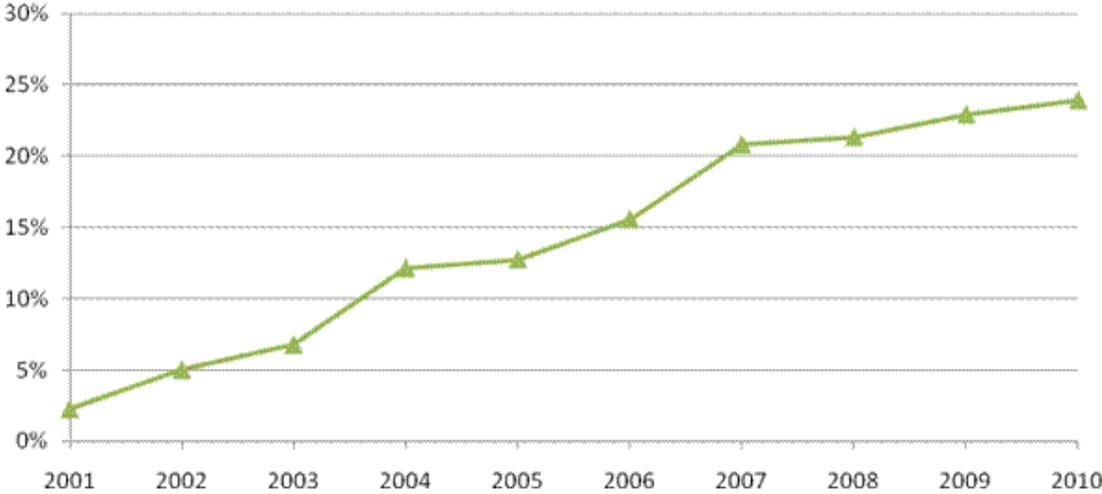
**Table 1. Acreage of GM corn by Region**

Region	2007	2008	2009	2010
<b>Aragon</b>	35,860	31,857	31,397	28,652
<b>Catalonia</b>	23,013	25,298	29,218	28,258
<b>Extremadura</b>	6,460	10,416	8,730	7,770
<b>Navarra</b>	5,327	5,150	4,691	4,477
<b>Castile-La Mancha</b>	3,659	4,739	3,417	3,187
<b>Others</b>	805	1,823	2,252	4,230
<b>Total</b>	<b>75,124</b>	<b>79,283</b>	<b>79,705</b>	<b>76,574</b>

Source: Ministry of Environment and Rural and Marine Affairs.

MON810 is resistant to infestations of the European corn borer, which are a problem for corn plantations mainly located in the Ebro River Basin in Northeastern Spain, as well as areas in the regions of Castile-La Mancha, and in second crop or late plantings in Andalusia. Aragon and Catalonia, both crossed by the Ebro River, are the primary GM corn growing regions in Spain representing about 75 percent of total BT corn area.

**Graph 2. MON 810 Area Share in Spain (%)**



Source: FAS Madrid based on Ministry of Environment and Rural and Marine Affairs data.

### **Section III. Plant Biotechnology Policy:**

Spain's has traditionally taken a science-based approach biotech regulatory process. With the EU policy agenda and rules being set in Brussels, Spain works hard to ensure that science is an important ingredient in the process, but in the end, Spain must abide by the EU-wide legislation. However, despite being one of the most open MS to biotechnology, Spain abstained in recent votes on biotech products at the EU level.

While EU regulations directly apply in all EU member countries, directives have to be transposed into national laws and they provide the opportunity for Member States countries to exercise some discretion without altering the basic scope of the EU directive.

The European Directive 2001/18 regarding GMOs was transposed to national regulation by [Law 9/2003](#) on confined use and voluntary release of genetically modified organisms. For EU-27 Biotech Regulatory Framework please see EU-27 report.

[National Law 9/2003](#) created and defined the responsibilities of the two relevant Authorities that weight-in on Spain's biotechnology decision making process, which are the National Biosafety Commission (CNB) and the Inter-ministerial Council for GMOs (CIOMG). Both institutions are chaired by Directorates General belonging to the Ministry of Environment and Rural and Marine Affairs.

#### **National Biosafety Commission (CNB)**

The CNB is an advisory body whose role is to assess the requests for cultivation, confined use and marketing of GMOs submitted at either the national or regional level. The CNB is comprised by representatives of different ministerial departments, representatives of the autonomous regions and experts in biotechnology. This Commission is chaired by the Director General of Environmental Quality and Assessment.

The composition of the CNB is available at:

<http://www.marm.es/es/calidad-y-evaluacion-ambiental/temas/biotecnologia/organismos-modificados-geneticamente-omg-/comision-nacional-bioseguridad/comision.aspx>

#### **Inter-ministerial Council for GMOs (CIOMG)**

The CIOMG takes a technical approach, and it is the competent authority to grant nationwide authorizations for confined use, voluntary release and marketing of Genetically Modified Organisms. This Council is chaired by the Director General of Sustainable Rural Development and it is comprised by representatives of the Ministries that are somehow related to biotechnology and it includes representatives from the Ministry of Environment and Rural and Marine affairs (MARM), the Ministry of Health and Social Policies, the Ministry of Industry, Tourism and Trade, the Ministry of Science and Innovation and the Ministry of Internal affairs.

The composition of the CIOMG is available at:

<http://www.marm.es/es/calidad-y-evaluacion-ambiental/temas/biotecnologia/organismos-modificados-geneticamente-omg-/consejo-interministerial-de-ogms/>

The CIOMG coordinates its work with the CNB and is responsible for the Exchange of information with the European Commission and with the Autonomous Communities. Spain has one of the most decentralized governments in Europe. It is made up of 17 autonomous communities and each community has considerable legislative authority. That is particularly true in the field of agriculture.

As far as the GMO policy is concerned, the national government is responsible for the marketing authorization for GMO and products containing GMO. It is also responsible for authorizing confined use and deliberate release of GMOs for research and development carried out under national programs as well as for the authorization of pharmaceutical products for humans or animals containing GMOs, and for the monitoring and control of field trials previous to the registration in the Commercial Varieties Catalogue.

The Autonomous Communities governments are responsible for authorizing confined use and deliberate release of GMOs for research and development and for the monitoring and control of these activities, with the exception of those belonging to the national government portfolio.

The National Government has exclusive responsibilities over the marketing authorization for GMO and products containing GMO.

### **Other Ministerial departments involved**

The Spanish Office of Vegetal Varieties, belonging to the Directorate General for Agriculture and Livestock Issues, is responsible for registering and monitoring GM seed for planting.

The EU is a signatory to the Biosafety Protocol, and Spain is an EU Member State. At national level, the Protocol is followed by the Ministry of Environment and Rural and Marine Affairs being the Deputy Direction General for Support and Coordination the focal point.

Within the MARM, the Sub directorate General for Animal Feed and Resources Preservation coordinates the National plan in feedstuffs whereas AESAN, the Spanish Food Safety and Nutrition Agency, ascribed to the Ministry of Health, Social Policy and Gender Equality is in charge of the food chain control.

Other Ministerial Departments weigh in to the GM decision process through the Inter-ministerial Council for GMOs (CIOGM) or the National Biosafety Commission (CNB).

## **Consultative Committee for GMO**

While the cultivation of GM crops is permitted, Spain is also strengthening public information and participation. The Consultative Committee for GMO (CPOGM) ascribed to the Inter-ministerial Council was created in October 2010 by [Ministerial Order 2616/2010](#). This participation body's main objective is to reassure public participation in GMO issue so that the Inter-Ministerial Council obtains first hand information of civil society representatives. The CPOGM can express its opinion on decisions to be taken and it is entitled to prepare proposals to be examined by the CIOMG.

The CPOGM is comprised by representatives of farmers' unions, agricultural cooperatives, consumers' organizations, labor unions, conservation NGOs, food industry, pharmaceutical industry, the entrepreneurial organization and the national network for rural development.

## **GM crops field register status**

Thus far, despite the fact that public field registers with the location of commercially grown biotech crops are compulsory in most MS, the only information available about commercial GE crops planting in Spain was the total area at the regional and national level, which was calculated based on GM seed sales records and it is publicly available at the Ministry of Environment and Rural and Marine Affairs website.

The implementation of a regulation to force those farmers who grow GE crops to register their plots is currently under discussion. This register would be likely managed by the regional governments. Farmers would have to declare in advance their intention to plant GE corn. According to press articles in national and regional media, farmer's declaration would need to include the exact location of the plot, as well as the measures they intend to enforce to avoid adventitious presence in neighboring crops. The additional paperwork linked to this requirement, as well as the fact that the farmers could be targeted (as in the past) for NGO intimidation, would discourage future plantings.

## **National Coexistence Rules**

There is no coexistence regulation enforced in Spain. A first draft of a coexistence decree was made public in 2004. The lack of consensus among the interested parties halted the implementation of a government-imposed national coexistence decree. Nevertheless, Spanish farmers continue to grow biotech corn without any environmental incident.

To date, coexistence has been managed following the good agriculture practices promoted by ANOVE, the National Association of Seed Breeders. ANOVE publishes on a yearly basis a guide containing good agricultural practices for BT corn cultivation. This guide includes practical tips to facilitate production traceability, labeling and coexistence. Hard copies of these guidelines are handed out along

with seed sacs by seed distributors and its latest electronic version is available on line at [http://www.anove.es/docs/maizbt\\_2011.pdf](http://www.anove.es/docs/maizbt_2011.pdf).

### **Cultivation opt out based on socioeconomic criteria**

Spain has reacted cautiously to the Commission proposal to allow EU MS governments to ban the cultivation of approved genetically modified organisms on grounds other than scientific safety assessments. Spain's main concerns regarding cultivation opt out, are the compatibility with the common internal market and the compliance with WTO rules. Some Spain's farmers associations have stated that cultivation opt out would have negative consequences in competitiveness, farmer's freedom of choice, EU's contribution to food security and EU's scientific potential.

### **Open field experimentation**

In Spain, about 28 field trials to be carried out throughout 2011 under Part B of the Directive 2001/18 have been notified to the Ministry of Environment and Rural and Marine Affairs for its approval up to July 2011. Agricultural field trials consist mainly in corn plots. Permits to test sugar beets, cotton, tobacco, potatoes and rice have also been requested. In Spain most of the open field trials are carried out by private companies.

The Spanish Ministry of Environment and Rural and Marine Affairs (MARM) does not publish the data of field trial locations, but provides the information to whoever requests it. In 2010 GE crops field trial location information was first released to the public by anti-biotech organizations and it resulted in the destruction of field trials and, by mistake, destruction of commercial corn plantings. Field trial data have also made public in 2011 by the same means, while in 2009 only the municipality location of field trials was given.

Whereas some may argue that this information increases transparency, some others believe that the release of field trial locations can target the trials for vandalism; precluding collection of the data required and jeopardizes research.

### **GM-free Zones**

Aside from the commercial production and research areas for GE crops, some municipalities/ provinces have declared themselves GM free zones. These zones are formed by the voluntary agreement of farmers to not plant GE crops in the particular area. It is our understanding that there is no legal enforcement mechanism connected to this declaration that would prevent a farmer from growing GE plants.

#### **Section IV. Plant Biotechnology Marketing Issues:**

Most of Spain's farmers associations are in favor of planting biotech crops as a tool to increase farms' competitiveness. Most farmers complain about the lack of events available, as they would benefit significantly from having access to herbicide tolerant varieties. Spain is one of the major livestock producers within the EU. Its structural shortfall of grains and oilseeds makes Spain's trade, feed and livestock sectors traditional supporters of biotech. There is not a strong reaction from retailers or meat consumers. Meat produced with GM feed does not have to be labeled.

Despite the fact that grain crops have the largest area cultivated in Spain, Spain's livestock industry is heavily dependent upon feed ingredient imports – which includes both GE and non-GE animal feed imports. Spain has a structural deficit of about 10 million tons of feed grains that varies every year depending on the demand of the feed sector, the domestic supply of grains and the availability of pastures.

As a result, the use of agricultural technologies such as biotechnology or irrigation systems to improve competitiveness and obtain consistent output levels are positively perceived and defended by a large majority of the farming sector. BT corn planted and harvested in Spain is utilized exclusively for the production of domestic compound feed and is labeled as containing "Genetically Modified Organisms".

Soybean meal is the primary source of proteins for livestock and domestic and European production of soybean is marginal. Spain's production of this oilseed is also of minor importance. Despite the availability of rapeseed meal produced in northern EU Member States, soybean meal remains the preferred protein ingredient both in terms of price and quality by feed compounders.

With a large trade deficit for soybean meal, used in animal feed rations, Spain imports large quantities of soybean meal and soybeans for crushing. Argentina is the main supplier of soybean meal, while Brazil followed by the US is the main supplier of soybeans. The large majority of the soybean products imported is GM, with the exception of those devoted to special markets niches.

According to Eurobarometer 2010, Spain's index of optimism for biotechnology/genetic engineering remains among the highest within the EU (74 percent) and so remains Spain's support for GM food (35 percent of respondents agreed or totally agreed that GM food should be encouraged).

#### **Labeling and traceability and control**

As a member of the European Union (EU), Spain strictly follows the rules set out in Regulation (EC) No 1829/2003 on Genetically Modified Food and Feed, and Regulation (EC) No 1830/2003 on the Traceability and Labeling of Genetically Modified Organisms. EU food labeling regulations provide for a 0.9 percent threshold for the "adventitious", that is, accidental and technically unavoidable,

presence of EU-authorized biotech event in a non-biotech food or feed. Products containing amounts above 0.9 percent must be labeled.

Since July 2011 the EU legislation sets at 0.1 percent the 'technical zero' level. This level corresponds to the lowest level of GE material taken into account by the EU reference laboratory for the validation of quantitative methods. It is only applicable to “adventitious” presence in feed material of non-approved GMOs for which an authorization procedure is pending in the EU or for which an authorization has expired.

Whereas most feed millers label feed as “containing GMOs”, the large majority of Food manufacturers, including multinational and national food manufacturers, with recognized labels have eliminated biotech products from food product composition.

Spain has a decentralized system for testing and controlling unauthorized presence of GMO in the feed and food chain. While the central government has a total control over the controls carried out in customs, the autonomous communities establish their own monitoring and sampling plans throughout the food and feed chain coordinated by national authorities. Sampling plans are based on risk assessment. Sampling is primarily done at the wholesale and the processing level.

Since a threshold level for adventitious GMO presence in seeds has not yet been set, Spain sources of GE seeds come down to South Africa, Romania, and Chile to a lesser extent.

#### **Section V. Plant Biotechnology Capacity Building and Outreach:**

FAS Madrid closely monitors and reports on significant developments in biotechnology, especially in terms of policy and marketing and continues providing information exchange and speakers to convey to the interested parties the benefits of biotech to face future challenges that include food supply and climate change.

#### **Section VI. Animal Biotechnology:**

There is no known research of development of GE animals for the food market. The Ministry of Environment and Rural and Marine Affairs keeps track of the GE animals used in confined facilities and publishes a complete list on their website. GE animal research since 1992 consists on mice, hogs or fish for medical purposes. Research in this field is carried out by both public and private research centers. GE animal are ruled by the same authorities as GE crops. The use of animals for medical research aimed at finding cures for diseases is found acceptable. Since no GE animal is being developed for food purposes, the debate on that regard has not sparkled yet.